

### **Amendment of the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-33. (Canceled)

34. (Currently amended) A method of treating a ~~pre-malignant lesion or a~~ malignant cancer in a subject, wherein the ~~pre-malignant lesion or~~ malignant cancer is characterized by the presence of activated matriptase, the method comprising:

- (a) obtaining a biological sample from a subject;
- (b) exposing the biological sample to a detectable ~~agent~~ antibody that recognizes and binds to activated matriptase;
- (c) detecting activated matriptase that is bound to the detectable ~~agent~~ antibody in the biological sample; and
- (d) administering to the subject an agent that blocks the activity of active matriptase.

35. (Currently amended) The method of claim 34, wherein the matriptase that characterizes the ~~pre-malignant lesion or~~ malignant cancer is produced by cells of an epithelial tissue.

36. (Currently amended) The method of claim 34, wherein the ~~pre-malignant lesion or~~ malignant cancer is present in a breast of the subject.

37. (Canceled)

38. (Canceled)

39. (Currently amended) The method of claim ~~38~~ 34, wherein the antibody binds specifically to activated matriptase but not to inactive matriptase.

40. (Canceled)
41. (Currently amended) The method of claim ~~40~~ 39, wherein the antibody is selected from M69 and M123.
42. (Currently amended) The method of claim ~~38~~ 34, wherein the antibody is labeled with a detectable label.
43. (Previously presented) The method of claim 42, wherein the antibody is labeled with a radioisotope or a fluorescent label.
44. (Previously presented) The method of claim 43, wherein the antibody is labeled with a radioisotope selected from the group consisting of  $^{62}\text{Cu}$ ,  $^{99}\text{Te}$ ,  $^{131}\text{I}$ ,  $^{123}\text{I}$ ,  $^{111}\text{In}$ ,  $^{90}\text{Y}$ ,  $^{188}\text{Re}$ , and  $^{186}\text{Re}$ .
45. (Previously presented) The method of claim 39, further comprising exposing the biological sample to one or more antibodies that recognize inactive, single-chain matriptase, and determining the ratio of the amount of activated matriptase that is specifically bound by antibodies to the total amount of matriptase that is specifically bound by antibodies.
46. (Previously presented) The method of claim 45, wherein the antibody that recognizes inactive, single-chain matriptase is M32.
47. (Previously presented) The method of claim 34, further comprising detecting the presence and or measuring the concentration in the biological sample of matriptase cognate inhibitor HAI-1.
48. (Previously presented) The method of claim 34, wherein the biological sample is obtained by biopsy, nipple aspirate, or removal of body fluid that has come into contact with cells of a pre-malignant lesion or a malignant cancer of the subject.

49. (Currently amended) The method of claim 34, wherein the ~~agent~~ antibody that blocks the activity of active matriptase binds specifically to and directly blocks the activity of activated matriptase.

50. (Canceled)